PATENT

Attorney Docket No. 015270-002120
Athena Docket No. 131-US-NEW??

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re application of:

PETER A. SEUBERT et al.

Application No.: 08/466,554

Filed: June 6, 1995

For: METHODS FOR AIDING IN THE DIAGNOSIS OF ALZHEIMER'S DISEASE BY MEASURING AMYLOID-β PEPTIDE (x-≥41) AND TAU

Examiner: Patricia Duffy

Art Unit: 1806

DECLARATION OF PETER A. SEUBERT PURSUANT TO 37 C.F.R. § 1.132

Assistant Commissioner for Patents
Washington, D.C. 20231

Sir:

I, PETER A. SEUBERT, declare:

considered 5/8/97 PAID.

1. I am an applicant for patent in the above-captioned application and a co-inventor of subject matter claimed in the application.

2. I have read the Office Action mailed June 25, 1996 in the above-captioned application. In that Office Action the Examiner asserted that the specification did not enable one to practice the screening assays claimed in the application because, in part, it was not apparent that one could collect a sufficient amount of cerebrospinal fluid (CSF) from a mouse in order to reproducibly detect Aβ(x-≥41). The Examiner pointed out that the specification showed the use of 100 μl of CSF in assays to detect Aβ(x-≥41). The Examiner also questioned whether it was possible to distinguish between human and murine forms of Aβ. I make this declaration to present facts that an assay to detect Aβ(x-≥41)

can be reproducibly performed using CSF from a single mouse and that the human and murine forms of Aβ are distinguishable.

3. Immunoassays to detect the amount of Aβ(x-≥41) in the CSF of a mouse are performed routinely in my lab at Athena Neurosciences by me and by persons working under my supervision. We routinely collect a 5 µl sample of CSF from a single mouse for use in these assays. The sandwich immunoassay we use, which is described in the specification, is sufficiently sensitive to detect Aβ(x-≥41) in these 5 µl samples.

4. Human and murine forms of Aβ can be distinguished. We have developed an antibody, which we refer to as 3D6, directed to an epitope containing amino acids 1-5 of Aβ. Aβ in humans has an arginine at position 5. Aβ in mice has a glycine at position 5. 3D6 does not recognize secreted APP or full length APP, but detects only Aβ species with an amino-terminal aspartic acid. The antibody 3D6 shows no cross-reactivity to the endogenous murine Aβ peptide at concentrations up to 1 ng/ml.

5. I hereby declare that all statements made herein of my own knowledge are true, and that all statements made on information and belief are believed to be true; and, further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application of any patent issued thereon.

Date: December 16, 1996

Peter A Seubert

Peter A. Seubert

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